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10/587,201	05/15/2007	Jean-Pierre Sachetto	SACH3001/ESS	8441

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EXAMINER	
HUGHES, ALICIA R	
ART UNIT	**PAPER NUMBER**
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/587,201	SACHETTO ET AL.	
	Examiner	Art Unit	
	Alicia R. Hughes	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,13-22,25,30 and 31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10, 13-22, 25, and 30-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 1-10, 13-22, 25, and 30-31 are pending and the subject of this Office Action.

Objections

The title of the invention, "Pharmaceutical Composition," is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Rejections - 35 U.S.C. §112.1

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

First 112, First Paragraph First Rejection

Claims 30-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are enabled for the treatment of chronic inflammatory conditions, hyperlipidaemia, hypertriglyceridaemia, asthma, and bipolar disorder. However, the claimed

prophylaxis of the same, *supra*, is not supported by the specification. As a result, the effect of performing the invention by one skilled in the art would be that of undue experimentation.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The Board also stated that although the level of skill in organic chemistry is high, the results of experiments to discover treatments for the illnesses and conditions recited in claim 30, is unpredictable. While all of the Wands factors are considered, a sufficient amount for a *prima facie* case is discussed below.

The applicant documentation to support the treatment of the referenced conditions as set forth in claim 30 (Specification, pages 6 and 8). However, the applicant has failed to enable the prophylaxis.

As such, the art of the claimed invention lacks predictability because the claim as written to include prevention requires undue experimentation.

First 112, First Paragraph Second Rejection

Claims 30-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The relevant factors are addressed below on the basis of comparison of the disclosure, the claims and the state of the prior art in the assessment of undue experimentation.

While the state of the art is relatively high with regard to the treatment of specific neoplasms, (a.k.a., cancers), the state of the art with regard to treating cancer broadly is underdeveloped. In particular, there is no known anti-cancer agent or combinations thereof, that is effective against all cancer types. The Cecil reference (cited by Examiner on the attached form PTO-892), clearly shows that for the various known cancer types, there is not one specific chemotherapeutic agent or agents that is effective for each and every type of cancer or tumor, which is the subject matter encompassed by the present claims, Goldman, Lee, et al., Cecil Textbook of Medicine, Chapter 198, W.B.Saunders Company (2000)[hereinafter referred to as "Cecil"](see Cecil at page Table 198-5 at page 1065; Tables 198-6 and 198-7 at page 1066; Table 198-8 at page 10684 and Table 198-9 at page 1071).

The level of ordinary skill in the art is high and would include the skill possessed by a person holding a degree such as a doctor of medicine degree. However, given the state of the art as set forth above, the artisan is currently unaware of any one particular anti-cancer agent, or combinations thereof, that is effective in treating all known types of cancer.

The lack of significant guidance from the present specification or prior art with regard to

the treatment of all cancers or tumors in a patient with any known anti-cancer or anti-tumor formulation imparts a significant degree of unpredictability in practicing the invention as presently claimed.

The guidance given by the specification is to generally administer the claimed active agent(s) to treat cancers or tumors broadly.

None of the examples in the present specification address the treatment of any particular cancer type, much less cancers in general.

The complex nature of the subject matter to which the present claims are directed is exacerbated by the breadth of the claim. The claims are extremely broad due to the vast number of possible cancer/tumor types represented by the term "neoplastic disease".

The specification does not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with this claim. Applicants have failed to provide guidance and information to allow the skilled artisan to ascertain that the present active agent is effective against all types of cancers, (a.k.a., neoplastic deseases).

Further Burden on the Examiner for Making a Rejection Under 35 U.S.C. § 112 First Paragraph

As set forth in *In re Marzocchi*, 169 USPQ 367, 370 (CCPA 1971):

> "[A] [s]pecification disclosure which contains teaching of manner and process of making and using the invention in terms corresponding to the scope to those used in describing and defining subject matter sought to be patented must be taken as in compliance with enabling requirement of first paragraph of 35 U.S.C. 112 *unless there is reason to doubt the objective truth of statements contain therein which must be relied on for enabling support*; assuming that sufficient reason for such doubt exists, a rejection for failure to teach how to make and/or use will be proper on that basis, such a rejection can be overcome by suitable proofs indicating that teaching contained in specification is truly enabling." (emphasis

added).

Here, the objective truth of the statement that neoplastic disease, of a non-restricted nature, could be successfully treated is doubted because the art (see the references relied upon *infra*) teaches that, at best, that only certain neoplastic diseases may be treated with only certain compounds or combinations thereof. Given this, the treatment of all known neoplastic diseases is merely a possibility and not a treatment outcome that could be accomplished with a reasonable degree of certainty or without a burden of undue experimentation, i.e., determining for which such diseases the claimed formulation could treat.

Summary

As the cited art and discussion above establish, practicing the claimed method in the manner disclosed by Applicants would not imbue the skilled artisan with a reasonable expectation that neoplastic diseases of all types could be effectively treated with the presently claimed formulations. In order to actually achieve the claimed objective, if at all possible, it is clear from the discussion above that the skilled artisan could not rely on Applicants' disclosure as required by 35 U.S.C. § 112, first paragraph in light of the state of the art. Given that the art fails to recognize and Applicant has failed to demonstrate that all known cancers/tumors could actually be treated, the skilled artisan would be faced with the impermissible burden of undue experimentation in order to practice this embodiment of the claimed invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-20 of U.S. Patent Application No. 11/411,236. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '236 patent application, like the instant invention, claims an essential oil, and essential oil adsorbent, a free water or water release remover, and essential oil adsorption/desorption regulator, an exothermic agent, a heat transfer inhibitor, an adsorption inhibitor, a base material for sheet formation, and an sheet for bonding. Albeit, the '236 application discloses Eucalyptus oil whereas the instant application discloses Rose Absolute, both are obvious variations of the other. Please see U.S. Patent 6,673,756 B2 [hereinafter referred to as "Sonnenberg et al"], Col. 5, lines 17-50, particularly lines 18, 31, and 50). Thus the composition disclosed in claims 2-20 of the '236 patent application overlap in scope with the composition articulated in claims 1-20 of the instant invention.

This is a provisional rejection, because the claims have not, in fact, been patented.

Claims 1-10 and 13-22 (composition claims) and 30-31 (method claims) are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 and 17 (composition claims) and 13-16 of U.S. Patent No. 5,792,795. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '795 patent, like the instant invention, claims a composition comprising omega-3-polyunsaturated fatty acids, particularly 5,8,11,14,17-eicosapentaenoic acid and 4,7,10,13,16,19-docosahexaenoic acid where a combination of the two comprises at least 60% by weight of composition. This differs from the instant application in that is requires at that 5,8,11,14,17-eicosapentaenoic acid and 4,7,10,13,16,19-docosahexaenoic acid comprise at least 75% of the

composition. Thus the composition disclosed in the '792 patent overlap in scope with the composition articulated in the instant invention. Similarly with regard to the method claims, the instant application is drawn to a method of treating a chronic inflammatory condition while the '795 patent is much more specific in that it is drawn to inflammatory bowel disease and thus the '795 patent and the instant application overlaps in scope with regard to the method claims, too.

In looking in continuity data, it is noted that applicant has pending applications encompassing the same or similar subject matter of the instant application. Applicant should review all subject matter considered the same or similar, and submit the appropriate Terminal Disclaimer(s). For example, pending patent applications with the same or similar subject matter include, but are not limited to 5,948,818.

Claim Rejections – 35 U.S.C. §103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10, 13-22, 25, and 30-31 are rejected under 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,502,077 [hereinafter referred to as "Breivik et al"](the reference is being considered in its totality).

Breivik et al teach a free fatty acid composition comprising at least 80% by weight of omega-3-polyunsaturated fatty acids, where at least 75% by weight of the total fatty acids comprise 5,8,11,14,17-eicosapentaenoic acid [hereinafter referred to as "EPA"] and

4,7,10,13,16,19-docosahexaenoic acid [hereinafter referred to as "DHA"] encased by a soft gelatin capsule (Col. 1, lines 5-10; Col. 2, lines 50-57; Col. 3, lines 36-41; Col. 11, lines 30-45). The free acids are produced by well-known hydrolyzation procedures (Col. 3, lines 59-60). The methodology for concentrating the EPA/DHA fractionation may utilized supercritical fluid extraction (Col. 3, lines 61-67 through Col. 4, lines 1-2). The composition notably uses collagen as a pre-treatment source (Col. 9, Table 10) and can be utilized in the treatment of hypertriglyceridaemia, hypertension, and cardiovascular, skin and inflammatory disorders (Col. 10, lines 36-47 through Col. 11, lines 1-7). Further, dosages may range from 1.0 to 10.0 grams depending on the body size and the seriousness of the condition to be treated (Col. 10, lines 42-45). Notably, the composition can contain extenders, surfactants and the like known to be utilized in the art of formulating a pharmaceutical composition (Col. 11, lines 17-20). The preparation is also disclosed (Col. 11, lines 28-45).

The use of Breivik et al do not disclose specifically soft gelatin capsules comprising fish gelatin, bovine gelatin and/or porcine gelatin. Nor do they disclose explicitly time release capsules. However, the adjustment of particular conventional working conditions such as these are mere matters of routine optimization and judicious selection well within the purview of one of ordinary skill in the art.

In view of the foregoing, it would have been *prima facie* obvious to one of ordinary skill in the art to conclude that the making and administration of a soft gelatin capsule containing EPA and DHA would be effective in the treatment of hypertriglyceridaemia.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia Hughes whose telephone number is 571-272-6026. The examiner can normally be reached from 9:00 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR of Public PAIR. Status information for unpublished applications is available through Public PAIR only. For information about the PAIR system, see http://pair-direct-uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

21 January 2008

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